DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JUL 27 2015

A & A Medical, Inc.
Jihad Mansour
Quality and Regulatory Manager
9370 Industrial Trace
Alpharetta, GA 30004

Re: K003949
Trade/Device Name: Medical Tacker, Model #R65-933
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW, GCJ
Dated (Date on orig SE ltr): May 8, 2001
Received (Date on orig SE ltr): May 14, 2001

Dear Mansour,

This letter corrects our substantially equivalent letter of July 25, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K003949

Device Name: TACKER

Indications For Use:

THIS DEVICE IS INDICATED FOR USE IN ENDOSCOPIC SURGERY PROCEDURES FOR URETHROPEXY, INCLUDING FIXATION OF PROSTATIC MATERIAL, APPROXIMATION OF TISSUES IN VARIOUS SURGICAL SPECIALTIES, SUCH AS REPAIR OF HERNIAS AND BLADDER NECK SUSPENSION

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K003949

JUL 2 5 2001

K003949

510(k) Summary
As Required by 21 section 807.92 (c)

1-Submitter Name: A & A Medical, Inc.
2-Address: 9370 Industrial Trace
Alpharetta, GA 30004
3-Phone: (770) 343- 8400
4-Fax: (770) 343- 8985
5-Contact Person: Jihad Mansour
6-Date summary prepared: December 15th, 2000
7-Device Trade or Proprietary Name: Tacker
8-Device Common or usual name: Endoscopic stapler
9-Device Classification Name: Endoscope and/or accessories
10-Substantial Equivalency is claimed against the following device:

- Origin Tacker system

11-Description of the Device:

The device is to be used by physicians in hospitals
The Tacker is a device that consists of one disposable component and two permanently implantable components. The disposable component is a 45cm long stainless steel tube. The first permanently implantable component is a helical fastener. The second permanently implantable component is a PROLENE non-absorbable "O" suture.
The instrument is designed for introduction and use through an appropriately sized trocar sleeve or larger with the use of an appropriate seal.

12-Intended use of the device:

This device is indicated for use in endoscopic surgery procedures for urethropexy, including fixation of prostatic material, approximation of tissues in various surgical specialties, such as repair of hernias and bladder neck suspension.

13-Safety and Effectiveness of the device:

This device (Tacker) is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)